

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

COTTINGHAM *et al.*

Appl. No.: (To be assigned)

Filed: (Herewith)

For: **Fusion Proteins Incorporating  
Lysozyme**

Confirmation No.: (To be assigned)

Art Unit: (To be assigned)

Examiner: (To be assigned)

Atty. Docket: 0623.0730002/EKS/BJD

**Preliminary Amendment**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In advance of prosecution in the above identified matter, Applicants seek entry of the following amendments. This Preliminary Amendment is provided in the following format:

(A) A clean version of each replacement paragraph/section/claim along with clear instructions for entry;

(B) Starting on a separate page, appropriate remarks. *See* 37 C.F.R. § 1.121 and MPEP § 714; and

(C) Starting on a separate page, a marked-up version entitled: "Version with markings to show changes made."

Please amend the application as follows:

***In the Specification:***

Please amend the specification as follows:

At page 1, after the title, please delete the first two paragraphs (appearing at lines 3-16 of page 1) and substitute therefor the following:

#### CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. Appl. No. \_\_\_\_\_ (Atty. Docket No. 0623.0730001/EKS/BJD), filed on December 21, 2001, which is the U.S. National Phase of International Application No. PCT/GB00/02459, filed internationally on June 23, 2000, which was published in the English language under PCT Article 21(2) as WO 01/00855 on January 4, 2001, which claims the benefit of U.S. Provisional Application No. 60/147,819, filed August 10, 1999, and which claims priority to GB Application No. 9914733.2, filed June 23, 1999, the disclosures of all of which are incorporated herein by reference in their entireties.

#### BACKGROUND OF THE INVENTION

##### Field of the Invention

The present invention relates to the production of peptides in the milk of transgenic mammals, for example non-human placental mammals.

##### Related Art

Polymers of amino acids concatenated via their amino and carboxyl groups form the basis for a variety of important biological compounds. Polymers of 3 to 100 amino acids are generally known as peptides, whilst larger polymers are known as proteins. This distinction is purely arbitrary, and polymers of up to about 110 amino acids can still be considered as "peptides". Thus, the term "peptide" as used herein refers to amino acid polymers of 3 to 110 amino acids. Peptides as

defined herein may be biologically active without requiring any further modification, or may form the building blocks for larger complex molecules by chemical modification into larger structures or by modification such as glycosylation. The term "peptide" is used herein to include biologically active and inactive polymers, which may or may not have undergone further modification.

In the specification at page 6, prior to the first line of the paragraph appearing at lines 20-25, please insert the following header for this paragraph:

#### BRIEF SUMMARY OF THE INVENTION

In the specification at page 8, prior to the first line of the paragraph appearing at lines 4-19, please insert the following header for this paragraph:

#### DETAILED DESCRIPTION OF THE INVENTION

In the specification at page 22, please delete the final two lines (appearing at lines 29-30) and substitute therefor the following:

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be illustrated by the following Examples, with reference to the figures, in which:

In the specification at page 25, prior to the first line of the header appearing at lines 5-7, please insert the following header for this section:

#### EXAMPLES

In the specification after page 39, and before the drawings, please insert the Abstract which is appended hereto as page 40.

In the specification after the drawings, please insert the paper copy of the Sequence Listing (pages 1-7).

***In the Claims:***

At page 36 and before claim 1, please delete the header appearing at line 1 and substitute therefor the following header:

WHAT IS CLAIMED IS:

***Remarks***

By the foregoing amendments, Applicants have amended the international application to provide the priority information as required by 37 C.F.R. § 1.78, to place the specification and claims into proper format for U.S. practice, and to insert the Abstract (which contains the same text as that appearing on the face page of the international application as published) and Sequence Listing into the appropriate locations in the specification. Hence, no new matter has been added by the foregoing amendments, and entry and consideration of the same are respectfully requested.

In accordance with 37 C.F.R. § 1.821(f), the paper copy of the Sequence Listing and the computer readable copy of the Sequence Listing submitted herewith in the above-mentioned application are the same. In accordance with 37 C.F.R. § 1.821(g), the submission of the Sequence Listing herewith includes no new matter.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Entry of the foregoing amendments and early consideration of the present application are earnestly solicited.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

Date: December 21, 2001

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**Version with markings to show changes made**

***In the Specification:***

In the specification at page 1, after the title, please insert the following:

-- The present application is a continuation of U.S. Appl. No. \_\_\_\_\_ (Atty. Docket No. 0623.0730001/EKS/BJD), filed on December 21, 2001, which is the U.S. National Phase of International Application No. PCT/GB00/02459, filed internationally on June 23, 2000, which was published in the English language under PCT Article 21(2) as WO 01/00855 on January 4, 2001, which claims the benefit of U.S. Provisional Application No. 60/147,819, filed August 10, 1999, and which claims priority to GB Application No. 9914733.2, filed June 23, 1999, the disclosures of all of which are incorporated herein by reference in their entireties.

**BACKGROUND OF THE INVENTION**

Field of the Invention --;

and at line 5, prior to the second full paragraph, please insert -- Related Art --.

In the specification at page 6, prior to line 20, please insert -- BRIEF SUMMARY OF THE INVENTION --.

In the specification at page 8, line 3, please insert -- DETAILED DESCRIPTION OF THE INVENTION --.

In the specification at page 22, line 28, please insert -- BRIEF DESCRIPTION OF THE DRAWINGS --.

In the specification at page 25, line 4, please insert -- EXAMPLES --.

In the specification at page 36, line 1, please delete "CLAIMS" and insert therefor -- WHAT IS CLAIMED IS: --.

In the specification after page 39, and before the drawings, please insert the Abstract which is appended hereto as page 40.

In the specification after the drawings, please insert the paper copy of the Sequence Listing (pages 1-7).

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